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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/578,900	05/26/00	CARULLI J	032796-019

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EXAMINER	
ANGELL, J	
ART UNIT	**PAPER NUMBER**
1633	9

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/578,900	Applicant(s) CARULLI ET AL.	
	Examiner Eirc Jon Angell	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-47 are pending in the application.

Applicant is advised that claim 18 was missing, therefore claims 19-48 were renumbered 18-47 to eliminate the missing claim. The renumbered claims are restricted in the following action. Also applicants are advised that claim 2 is in improper form because it depends on itself. It was assumed that claim 2 was intended to depend upon claim 1.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1, 2, 6 and 7 drawn to a method of identifying a molecule that binds to or inhibits binding to a protein and is involved in lipid regulation, classified in class 435, subclass 6, for example. Note that claim 7 includes the recitation "wherein the candidate molecule is a protein, an mRNA, or an antisense nucleic acid." This claim encompasses 3 different inventions. Applicants are required to elect one of the recited molecules (inventions) for examination.

   II. Claim 3, drawn to an antibody, classified in class 435, subclass 7.1, for example.

   III. Claims 4 and 5, drawn to a method of identifying protein expression level, classified in class 800, subclass 3, for example.

   IV. Claims 8 and 9, drawn to a method of screening agents which modulate lipid levels *in vivo* by administering a nucleic acid, classified in class 514, subclass 44, for example.

V. Claim 10, drawn to a method of screening an agent for modulating lipid levels using a protein, classified in class 435, subclass 4, for example.

VI. Claims 11 and 12, drawn to a method of developing a treatment of lipid-mediate disorders by identifying molecules that bind a polypeptide, classified in class 435, subclass 7.1+, for example. Note that claim 12 recites, "wherein the molecule inhibits or enhances the function of the amino acid." This claim encompasses two different inventions. Applicants are required to elect either "inhibits" or "enhances" for examination.

VII. Claims 13-15, drawn to a method of pharmaceutical development by comparing hosts, classified in class 800, subclass 3, for example. Note that claim 14 recites, "wherein the host is a cell-free extract, a cell, or an animal." This claim encompasses 3 different inventions: a cell-free extract, a cell, and an animal. Applicants are required to elect one invention for examination.

VIII. Claims 16 and 17, drawn to a method of regulating lipid levels in a host by administering protein comprising SEQ ID NO: 4, classified in class 514, subclass 2, for example.

IX. Claims 18 and 19, drawn to a method of treating or preventing a lipid-mediated disorder using a nucleic acid comprising SEQ ID NO: 2, classified in class 514, subclass 44.

X. Claims 20-23, drawn to treating or preventing arteriosclerosis using an amino acid comprising SEQ ID NO: 4, classified in class 514, subclass 44, for example.

XI. Claims 24 and 25, drawn to treating or preventing a lipid-mediated disorder using a molecule that binds to a nucleic acid comprising SEQ ID NO: 2, classified in class 514, subclass 44, for example.

XII. Claim 26, drawn to a method of treating or preventing a lipid-mediated disorder using an antibody, classified in class 530, subclass 387.1+, for example.

XIII. Claims 27 and 28, drawn to a diagnostic screen using nucleic acid of HBM, classified in class 435, subclass 6.

XIV. Claim 29, drawn to a diagnostic screen using antibodies with specific reactivities to HBM and Zmax1 protein, classified in class 530, subclass 387.1+, for example.

XV. Claims 30-32, drawn to a method of expressing HBM protein in tissue, classified in class 530, subclass 387.1+, for example.

XVI. Claims 33-35, drawn to a method of modulating lipid levels in a subject using HBM or Zmax1 protein, classified in class 514, subclass 2-21, for example. Note that claim 33 recites, "by administering an HBM protein or a Zmax1 protein". This claim encompasses two inventions: administering HBM protein and administering Zmax1 protein. Applicants are required to elect one invention for examination.

XVII. Claims 36-38, drawn to a method of modulating lipid levels using a regulator of HBM1 or Zmax1 activity, classified in class 514, subclass 2-21 and 44, for example.

XVIII. Claims 39-44, drawn to a composition for treating a subject with a lipid-mediated condition using an agent that regulates lipid levels, and a treatment using the

composition, classified in class 424, subclass 130.1+ and 198.1 and class 514, subclass 2-21, for example.

XIX. Claims 45-47, drawn to a combination therapy for treating a subject with a lipid-mediates condition using an agent that regulates HBM or Zmax1 and an agent which regulates a lipoprotein, classified in class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II, IX-XI, XVIII and XIX are drawn to methods of treatment. Inventions I, III-VII, XIII and XIV are drawn to screening methods. Invention XII is drawn to an antibody. Invention XV is drawn to a method of expressing a protein. Inventions VIII, XVI and XVII are drawn to methods of regulating or modulating lipid levels in a subject. These general categories of inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different categories of inventions have different modes of operation, different functions and different effects. For instance, the function of treatment methods is to ameliorate a disease or pathology in a subject, antibodies have several functions including protein binding, the function of screening methods is to identify specific agents, the function of a method of expressing protein is to express a specific protein, the function of regulating or modulating lipid levels in a subject is to increase or decrease lipid levels of a subject regardless if the subject is diseased or not. The general categories have distinct functions; therefore, the inventions of each category are

unrelated and patentably distinct from the inventions of the other general categories and restriction is proper.

Inventions II, IX-XI, XVIII and XIX are all drawn to methods of treatment; however, each is distinct from the other because the methods are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, such as the use of different reagents or different effects. For instance, Invention II utilizes antibodies, Invention IX utilizes nucleic acid, Invention X utilizes amino acids, Invention XI utilizes a molecule that binds to a nucleic acid (molecule could be something other than a nucleic acid, amino acid, or antibody), Invention XVIII utilizes a pharmaceutical composition comprising an agent that regulates lipid levels, and Invention XIX utilizes an agent which regulates HBM or Zmax1 (the agent may be one that does not regulate lipid levels) and an agent which regulates a lipoprotein. These inventions utilize different reagents; therefore, they have different modes of action and are patentably distinct.

Inventions I and III-IX are all drawn to screening methods; however, each is distinct from the other because the methods are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation or different functions. For example, Invention I is

a screen to identify a molecule that binds to or inhibits binding to a protein, Invention III is a screen comparing protein expression levels in two different hosts for the purpose of identifying proteins involved in lipid regulation, Invention IV is a screen involving the administration of a nucleic acid to a subject, Invention V is a screen to identify agents that modify lipid levels using a protein, Invention VI is a screen to identify molecules that bind to a protein, Invention VII is a screen involving administering an agent to one host and then comparing that host to a different host, Invention XIII involves using a nucleic acid on a sample (not in a subject), and Invention XIV is a screen involving the use of antibodies. These inventions are patentably distinct because they utilize different reagents (different modes of operation) or have different functions; therefore, restriction is proper.

Inventions VIII, XVI and XVII are all drawn to methods of regulating lipid levels; however, they are patentably distinct because they have different modes of operation. For instance, Invention VIII involves administering of protein to a somatic or germ cell, Invention XVI involves administering a protein to a subject, and Invention XVII involves administering a modulator of HBM or Zmax1 activity (modulator may be one that is not a protein). Therefore, restriction is proper.

Additionally, because many of these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Also, these inventions are distinct for the

reasons given above and the search required for each Invention is not required for another Invention, restriction for examination purposes as indicated is proper.

Claims 9, 17, 19, 21 and 25 are generic to a plurality of disclosed patentably distinct species comprising the following animals: livestock, primates, humans, canines, felines, rodents, birds, reptiles, fish and amphibians. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Clark can be reached on (703) 305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angel, Ph.D.
September 28, 2001

REMY YUCEL, PH.D
PRIMARY EXAMINER